

In re: Ideker
Serial No.: 10/648,162
Filed: August 26, 2003
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In the drawings:

Page 2 of the Action requires new corrected drawings in compliance with 37 CFR 1.121(d). Replacement Figures 1, 2 and 4 are attached, and Applicant requests that the drawing objection be withdrawn.

Attached: Three (3) drawing sheets.

REMARKS

I. Status of the Application

A. Status of the Drawings

Page 2 of the Action requires new corrected drawings in compliance with 37 CFR 1.121(d). New Figures 1, 2 and 4 are attached, and Applicant requests that the drawing objection be withdrawn.

B. Status of the Claims

Claims 1-54 are pending in the application. Claims 1-3, 5-11, 13-20, 22-26, and 28-37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,915,156 to Christini et al. ("Christini"). Claims 4 and 27 stand rejected under 35 U.S.C. § 102(e) as being unpatentable over Christini in view of U.S. Patent No. 6,965,797 to Pastore et al. ("Pastore"). Claims 12 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christini in view of U.S. Patent No. 6,823,213 to Norris et al. ("Norris"). Claims 38-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christini in view of Pastore and Norris.

Applicants submit that the pending claims are in condition for allowance based on the above amendments and for the reasons that follow.

II. The Rejections Under 35 U.S.C. § 102/103

Claim 1 recites a method for selectively initiating interventional therapy in a subject, including:

chronically detecting electrical activity in first and second cardiac regions in the subject;

identifying discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and

initiating interventional therapy in the subject responsive to the identification of discordant alternans.

Claim 38 recites a computer program product corresponding generally to Claim 1.
Claim 18 recites a system for selectively initiating interventional therapy in a subject including:

a plurality of electrodes configured and sized to chronically detect electrical activity in first and second cardiac regions; and
a discordant alternans monitor operably associated with the electrodes, the discordant alternans monitor configured to identify discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and to initiate interventional therapy in the subject responsive to the identification of discordant alternans.

As discussed in the present application on page 6, lines 6-24 of the Specification and as shown in **Figure 6**, concordant alternans are, for example, present when different portions of the myocardial region are in phase with one another, and discordant alternans are present when different portions of the myocardial region are out of phase with one another. Applicants submit that Christini does not teach or suggest identifying discordant alternans based on a comparison of the electrical activity in the first and second cardiac regions as recited in independent Claims 1, 18 and 38.

In particular, Christini proposes the analysis of beat-pair to beat-pair differences at a single location, i.e., concordant alternans. Christini repeatedly emphasizes that "repolarization alternans can be detected from a single spatially-localized endocardial lead." See Christini, col. 6, lines 6-8; col. 6, lines 21-25 (cited on page 3 of the Action); and col. 10, lines 63-65. Although Christini proposes multi-electrode configurations, Christini states that its proposed method detects repolarization alternans "at the location of one of the electrodes." See, e.g., col. 4, lines 4-20 and col. 13, lines 59-65 (Claim 6). Christini discusses that odd numbered beats in each beat pair are subtracted from even numbered beats in the beat pair, and the sign of the difference is determined. Christini states that if this sign is consistent from one beat pair to an adjacent beat pair, then it is an indicator that there is a repeated repolarization alternation. See col. 6, lines 5-13. Christini only delivers an electrical stimulus if the sign of the difference in beat-pair to beat-pair magnitude is consistent. See col. 6, line 58-60. Accordingly, Christini does not teach or suggest that discordant alternans

are identified "based on a comparison of the electrical activity in the first and second cardiac regions" as recited in independent Claims 1, 18 and 38.

In addition, independent Claims 1, 18 and 38 recite that electrical activity in first and second cardiac regions in the subject is chronically detected. The Action cites column 2, lines 6-9 of Christini as defining repolarization alternans (RPA) as action potentials in different regions of the heart changing from concordant to discordant alternation. *See* the Action, page 3. However, Christini merely discusses that a change from concordant to spatially discordant alternans occurs as heart rate or pacing rate increases. *See* Christini, col. 2, lines 6-7. Because Christini teaches that discordant alternans occur only as the heart rate or pacing rate increases, Christini teaches away from the chronic detection of electrical activity in first and second cardiac regions, which in some embodiments of the current invention, may occur regardless of heart rate or pacing rate.

Applicant submits that independent Claims 1, 18 and 38 are patentable at least for the reasons discussed above. Claims 2-17, 19-37, and 39-54 are patentable at least per the patentability of the claims from which they depend. Accordingly, Applicant requests that the rejections under §§ 102/103 be withdrawn. In addition, various dependent claims are separately patentable for at least the reasons that follow.

In particular, Claims 2, 25 and 39 each recite that the component of the detected electrical activity in which discordant alternans are identified is a duration, shape and/or amplitude of the STT segment. Christini discusses T-wave alternans (col. 2, lines 20-26), but makes no reference to STT segments. Accordingly, Christini cannot anticipate Claims 2, 25 and 39 and Claims 2, 25 and 39 are separately patentable.

III. Conclusion

In view of the foregoing amendment and remarks, the Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Laura M. Kelley".

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A handwritten signature in black ink, appearing to read "Carey Gregory".

Carey Gregory